FEB 1 8 2000

510(k) Summary

Galil Medical - CRYO-HIT™ System

510(k) Number

K993965

Company Name:

Galil Medical Ltd.

Contact Person:

Dr. Roni Zvuloni,
IP, QA & Regulatory Manager
Telephone: +972-4-959 10 80
Fax: +972-4-959 10 77

Trade Proprietary Name:

CRYO-HIT™.

Classification Name:

CRYOSURGICAL UNIT

Classification:

GEH

Predicate Devices:

CRYO-HIT™200 System

Indication for Use:

The CRYO-HIT™ System for MRI is intended for cryogenic destruction of tissue during surgical procedures. It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology, thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The CRYO-HIT™ System for MRI, like the already cleared CRYO-HIT™ System has the following specific indications:

Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia "BPH")

Oncology (ablation of cancerous or malignant tissue, and ablation of benign tumors, and palliative intervention)

Dermatology (ablation or freezing of skin cancers and other cutaneous disorders)

Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)

General surgery (destruction of warts or lesions, palliation of tumors of the oral cavity, rectum and skin, and ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorroids, anal fissures, perianal conylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, and recurrent cancerous lesions)

Thoracic surgery (ablation of arrhythmic cardiac tissue, and ablation of cancerous lesions)

Proctology (ablation of benign or malignant growths of the anus or rectum, and ablation of hemorrhoids)

The CRYO-HIT™ System for MRI may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to locate the target tissue, ensure correct placement of the probes and monitor the size of the iceball. The MRI or ultrasound device provides real-time visualization of the cryosurgical procedure.

Device Description:

The CRYO-HIT™ system for MRI is the exact same device as Galil Medical LTD's cleared System (K991517) except for the following technological modification: (1)- the additional MRI kit and (2) the availability of more probe types: 2 mm probe, surface probe, and disk shaped probe (The probes cleared for use with the modified CRYO-HIT™ System under K991272 include the same 2 mm probes, surface and disk shape probes, proposed for use with the CRYO-HIT™ for MRI).

Substantial Equivalence: The CRYO-HIT™ System for MRI has the same intended use, and very similar principle of operation and technological characteristic as the cleared CRYO-HIT™ 200 System (K991517). Therefore, the CRYO-HIT™ System for MRI is substantially equivalent to the CRYO-HIT™ 200 System (K991517).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2000

Galil Medical, Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson
555 Thirteenth Street
Washington, DC 20004

Re: K993965
Trade Name: CRYO-HIT™
Regulatory Class: II
Product Code: GEH
Dated: November 23, 1999
Received: November 23, 1999

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

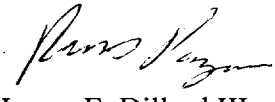
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K993965

Device Name: CRYO-HIT™ System

Indications for Use:

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993965

Prescription Use X
(Per 21 CFR 801.109)

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K955965